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09/531,113	03/22/2000	Joseph R. Byrum	38-21(15761)B (16517.001)	4899
66057 7590 02/10/2009 MONSANTO COMPANY (A&P) 800 N. LINDBERGH BOULEVARD MAILZONE E2NA ST. LOUIS, MO 63167			EXAMINER WILDER, CYNTHIA B	
			ART UNIT 1637	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* JOSEPH R. BYRUM, GREGORY R. HECK, and  
THOMAS J. LA ROSA

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Appeal 2009-1323  
Application 09/531,113  
Technology Center 1600

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Decided<sup>1</sup>: February 10, 2009

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Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and  
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1 and 8-13, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

## STATEMENT OF THE CASE

The claims are directed to a substantially purified nucleic acid molecule. Claims 1 and 10 are illustrative:

1. A substantially purified nucleic acid molecule that encodes a soybean protein comprising a nucleic acid sequence of SEQ ID NO: 5981.

10. A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

No evidence is relied upon on this record (*see* Ans. 3; App. Br. 12).

The rejection as presented by the Examiner is as follows:

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

We affirm.

## ISSUE

Is the percent identity that SEQ ID NO: 5981 shares with a nucleic acid sequence that encodes a protein obtained from water-stressed *Glycine max* sufficient to support a utility for Appellants' claimed invention?

## FINDINGS OF FACT

FF 1. The Examiner finds that

[t]he claimed subject matter is not supported by a specific[,] substantial or a well established utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a “real world” use.

(Ans. 3.)

FF 2. The Examiner finds that while Appellants have disclosed “a number of general utilities for the nucleic acid molecule”; “[n]one of these[] asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed” (Ans. 3-4).

FF 3. The Examiner finds that “no direct connection is made between the claimed sequence or any of the numerous utilities claimed . . . [t]hus, further research is required to determine the specific utility of the claimed nucleic acid sequence” (Ans. 4).

FF 4. The Examiner finds that Appellants’ Specification discloses that “one or more of the 48,629 nucleic acids of the present invention, maybe utilized as markers or probes to detect polymorphisms” (Ans. 7). In this regard the Examiner finds that Appellants’ Specification

does not explain why any of the [sic] these nucleic acid molecules disclosed in the specification, or more specifically a nucleic acid molecule comprising the sequence of SEQ ID NO: 5981 would in fact be useful in detecting a polymorphism or whether the claimed nucleic acid molecule can, in fact, be used to detect any polymorphism, whatsoever. The specification generally teaches using the claimed nucleic acid molecules to identify a polymorphism, but fails to teach that a polymorphism

could in fact be detected, or whether a “specific” polymorphism could be detected.

(*Id.*)

FF 5. The Examiner finds that even if a polymorphism could be detected since Appellants’ disclosure

provides no information with regards to the genes represented by the nucleic acid or the encoded protein . . . [or] evidence characterizing those polymorphisms or information concerning the gene(s) represented by the claimed nucleic acid molecule(s) which may or may not comprises [sic] the polymorphisms or some type of association of the polymorphism with a genetic trait, disease or condition . . . . [f]urther research would be required to determine what said detection of polymorphism indicates.

(Ans. 7-8.)

FF 6. The Examiner finds that Appellants’ Specification “provides no evidence or support anywhere to establish that the sequence of SEQ ID NO: 5981 shares 94 percent identity to any nucleic acid molecule, especially, a protein from water-stressed *Glycine max*” (Ans. 9). In this regard, the Examiner finds that Appellants’ Specification “does not recite, disclose or even suggest any association of, or function of any nucleic acid molecule being involved in water-stress[ ]” (Ans. 9-10).

FF 7. The Examiner finds that “in Appellants’ remarks submitted on 09/07/2006, Appellants disclose that the nucleic acid molecule encoding a protein from water stressed *Glycine max* was disclosed in an unpublished 2005 study (see page 3). The instant invention however was filed on March 22, 2000” (Ans. 10).

## PRINCIPLES OF LAW

“Enablement, or utility, is determined as of the application filing date.” *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. . . . Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility. *See In re Bundy*, 642 F.2d 430, 433.

*In re Brana*, 51 F.3d at 1566.

To fulfill the utility requirement under 35 U.S.C. § 101, a claimed invention must have a specific and substantial utility. *See In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). A substantial utility is one that “show[s] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.” *In re Fisher*, 421 F.3d at 1371.

A specific utility is a

use which is not so vague as to be meaningless. Indeed, one of our predecessor courts has observed “that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for technical and pharmaceutical purposes’ unsuccessfully relied upon by the appellant in *In re Diedrich*.” *In re Kirk*, 376 F.2d 936, 941 (C.C.P.A. 1967). Thus, . . . an asserted use must also

show that the claimed invention can be used to provide a well-defined and particular benefit to the public.

*In re Fisher*, 421 F.3d at 1371.

## ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 10.

Claim 10 is drawn to a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

Based on the foregoing facts (FF 1-7), the Examiner concludes that claim 10 is not “supported by either a specific and/or substantial utility or a well established utility” and since the claimed invention lacks utility “one skilled in the art would not know how to use the claimed invention based on the lack of utility” (Ans. 3 and 6).<sup>2</sup>

Appellants content “that SEQ ID NO: 5981 has 94 percent identity to a sequence obtained from water-stressed *Glycine max*” (App. Br. 4). In support of this contention Appellants direct attention to pages 2-3 of a response they filed with the Office on September 7, 2006 (*id.*). The Examiner finds, however, that “in Appellants’ remarks submitted on 09/07/2006, Appellants disclose that the nucleic acid molecule encoding a

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<sup>2</sup> The Examiner’s rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement, is presented simply as a corollary of the finding of lack of utility (*see* Ans. 5-6). Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the § 112 rejection.

protein from water stressed *Glycine max* was disclosed in an unpublished 2005 study (see page 3). The instant invention however was filed on March 22, 2000” (FF 7). “Enablement, or utility, is determined as of the application filing date.” *In re Brana*, 51 F.3d at 1567 n.19.

Further, the Examiner finds that Appellants’ Specification “provides no evidence or support anywhere to establish that the sequence of SEQ ID NO: 5981 shares 94 percent identity to any nucleic acid molecule, especially, a protein from water-stressed *Glycine max*” nor does it “recite, disclose or even suggest any association of, or function of any nucleic acid molecule being involved in water-stress[ ]” (FF 6).

Accordingly, we are not persuaded by Appellants’ contention that since SEQ ID NO: 5981 shares 94 percent identity to a nucleic acid sequence encoding a protein obtained from water-stressed *Glycine max*, the invention of claim 10 has a substantial and credible utility “because SEQ ID NO: 5981 can be used to isolate genes, map genes, and determine gene function associated with . . . water stress” (App. Br. 6).

In sum, all of Appellants’ contentions relate to the percent identity that SEQ ID NO: 5981 shares with a nucleic acid sequence that encodes a protein obtained from water-stressed *Glycine max*. This relationship, however, was not disclosed in Appellants’ Specification, nor is there evidence that it could have been known at the time of Appellants’ filing date (see FF 6 and 7). Accordingly, we are not persuaded by Appellants’ contentions.



### CONCLUSION OF LAW

The percent identity that SEQ ID NO: 5981 shares with a nucleic acid sequence that encodes a protein obtained from water-stressed *Glycine max* is *not* sufficient to support a utility for Appellants' claimed invention.

For the foregoing reasons, we affirm the rejection of claim 10 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility. Because they are not argued separately, claims 1, 8, 9, and 11-13 fall together with claim 10.

### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

### AFFIRMED

Ssc:

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